



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,098	10/30/2003	Florenziano Della Torre	P/2528-13	2668
2352	7590	11/21/2006	EXAMINER	
OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,098

Applicant(s)

TORRE, FLORENZIANO DELLA

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,561,997 to Weitzel et al in view of US 4,828,543 to Weiss et al.

In the specification and figures, Weitzel discloses the device substantially as claimed by applicant. With regard to claim 1, Weitzel discloses a hemofiltration or dialysis system that acts as a renal assist device (see column 2, lines 15-20). The apparatus comprises a hemofiltration system 300 with a blood path 58/72 that connects to pass blood to and from a patient 100, pump 52, a container 60 and pump 56 for infusing anticoagulant (corresponding to applicant's means for adding drugs), containers 62, 64, pump 56 for replacement fluid (corresponding to applicant's means for feeding refill liquid), and blood filter 48 (see FIG 1, column 4, line 40 to column 5, lines 20).

Weitzel fails to disclose an oxygenating device connected upstream of the blood filter. However, Weiss discloses an extracorporeal treatment device that uses mass transfer devices such as filters and oxygenators to withdraw, treat, and return blood to the patient. In particular, the device seeks to circulate, cleanse, and oxygenate a patient's blood in the event of blood system failure (see column 1, line 63 to column 2,

line 11). The apparatus includes a blood path (see line 102 in FIG 9), pumps 104, 106, and treatment means connected in series (142A, 142B, 142C). The treatment means may comprise blood filters or a blood oxygenator (see column 25, line 35 to column 26, line 52, column 32, lines 12-14). The treatment means connected in series (wherein the oxygenator may be located upstream of the filter) allow for a combination of a plurality of treatments that replace a patient's damaged blood system (see column 26, lines 37-52, column 1, line 63 to column 2 line 11). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an oxygenator upstream of the filter as disclosed by Weiss in the apparatus disclosed by Weitzel in order to provide a plurality of treatments to replace the function of a patient's damaged blood system, as taught by Weiss.

With regard to claim 2, Weiss illustrates that the treatment means 142 are disposed downstream of pump 104 (see FIG 9).

With regard to claims 3 and 4, Weiss illustrates that several treatment means may be disposed in series downstream of pump 104, indicating that the oxygenator may be placed upstream of the filter (see FIG 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the oxygenator upstream of the filter, since it has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP 2144.04. In the instant case, Weiss discloses that the mass transfer devices (which transfer solutes or oxygen) are interchangeable, indicating that the treatment devices may be connected in any order in series.

With regard to claim 5, Weitzel fails to disclose an oxygen tank and an outlet connected to an oxygenator. Weiss discloses an extracorporeal blood treatment system with a blood inlet 134, outlet 136, and membrane oxygenator with an O₂ tank 276 as the oxygen supply and a CO₂ outlet 150 in order to drain spent oxygen and CO₂ from the oxygenator (see FIG 8, column 25, line 60 to column 26 line 68). Therefore, it would have been obvious to someone of ordinary skill in the art at the time the invention was made to add an oxygenator with the associated oxygen supply and venting components disclosed by Weiss in the apparatus disclosed by Weitzel, in order to provide a plurality of treatments to replace the function of a patient's damaged blood system and to provide a means for venting CO₂ and unused O₂, as taught by Weiss.

With regard to claim 6, applicant claims the operation of the blood pump to create a particular flow rate. Such a limitation is considered by the examiner to be a statement of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed fails to differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Weitzel specifically discloses that the blood pump 52 may be set to pump blood at a rate of 10mL/min up to 1000 mL/min (see column 7, lines 34-67). Weitzel's disclosure of possible pump rates indicate that the pump 52 is capable of performing at the rate claimed by applicant, meeting the limitations of the claims.

With regard to claim 7, Weitzel fails to disclose an oxygen tank and an outlet connected to an oxygenator. Weiss discloses an extracorporeal blood treatment system

Art Unit: 3761

with a blood inlet 134, outlet 136, and membrane oxygenator with an O₂ tank 276 as the oxygen supply and a CO₂ outlet 150 in order to drain spent oxygen and CO₂ from the oxygenator (see FIG 8, column 25, line 60 to column 26 line 68). Therefore, it would have been obvious to someone of ordinary skill in the art at the time the invention was made to add an oxygenator with the associated oxygen supply and venting components disclosed by Weiss in the apparatus disclosed by Weitzel , in order to provide a plurality of treatments to replace the function of a patient's damaged blood system and to provide a means for venting CO₂ and unused O₂, as taught by Weiss.

Response to Arguments

3. Applicant's amendment filed 21 September 2006 have been entered and considered.
4. Applicant's arguments with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

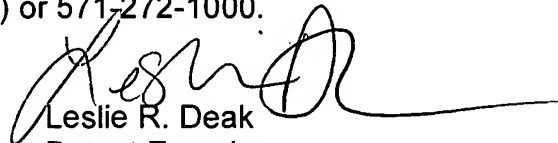
Art Unit: 3761

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leslie R. Deak
Patent Examiner
Art Unit 3761
14 November 2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

